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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PILLSBURY WINTHROP, LLP
P.O. BOX 10500
MCLEAN, VA 22102

EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/743,956	Applicant(s) SMITH ET AL.	
	Examiner Juliet Einsmann	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-9, claim(s) 1-5, in part, drawn to a method for diagnosis of a single nucleotide polymorphism in NK1R. These claims recite 9 different single nucleotide polymorphisms in NK1R. Each group designated herein is inclusive of one of those polymorphisms. Upon election, applicant should indicate which polymorphism is selected for examination. This, and each requirement that follows herein, is a restriction requirement, not a requirement for election of species.

Groups 10-18, claim(s) 6, in part, drawn to a method for use in assessing the predisposition and/or susceptibility of an individual to diseases mediated by NK1R ligands. This claim recites 9 different single nucleotide polymorphisms in NK1R. Each group designated herein is inclusive of one of those polymorphisms. Upon election, applicant should indicate which polymorphism is selected for examination.

Groups 19-27, claim(s) 7-11, in part, drawn to allele specific oligonucleotides. These claims recite 9 different single nucleotide polymorphisms in NK1R. Each group designated herein is inclusive of one of those polymorphisms. Upon election, applicant should indicate which polymorphism is selected for examination.

Group 28, claim(s) 12, drawn to an allelic variant of human NK1R polypeptide having a C-terminal deletion of 26 amino acids.

Groups 29-37, claim(s) 13, in part, drawn to methods of treating a human in need of treatment with a NK1R ligand antagonist drug. This claim recites 9 different single nucleotide polymorphisms in NK1R. Each group designated herein is inclusive of one of those polymorphisms. Upon election, applicant should indicate which polymorphism is selected for examination.

Groups 38-46, claim(s) 14, in part, drawn to methods of preparing a medicament for treating a NK2-mediated disease. This claim recites 9 different single nucleotide polymorphisms in NK1R. Each group designated herein is inclusive of one of those polymorphisms. Upon election, applicant should indicate which polymorphism is selected for examination.

Groups 47, claim(s) 15, in part, drawn to an NK1R ligand antagonist drug.

Groups 48-56, claim 16, in part, drawn to a computer readable medium having stored thereon a nucleic acid. This claim recites 9 different single nucleotide polymorphisms in NK1R. Each group designated herein is inclusive of one of those polymorphisms. Upon election, applicant should indicate which polymorphism is selected for examination. In addition, the claim recites a number of particular sequences, identified by either SEQ ID NO or EMBL Accession number. For whichever polymorphism is selected, applicant should identify the sequences that would comprise the polymorphism of interest.

Groups 57-65, claims 17-18, in part, drawn to a method for performing sequence identification which requires a nucleic acid comprising one of nine specifically recited polymorphisms. Each group designated herein is inclusive of one of those polymorphisms. Upon election, applicant should indicate which polymorphism is selected for examination. Furthermore, claims 17 and 18 recite final process steps which require comparison with "at least one other nucleic acid or polypeptide to determine sequence identity." It is not clear how one determines sequence identity between a nucleic acid and a polypeptide. If applicant is to elect an invention as disclosed in claims 17-18, applicant is required to further elect a single nucleic acid sequence for examination and applicant is required to elect either methods of comparison with a nucleic acid or comparison with a polypeptide.

2. The inventions listed as Groups 1-65 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(i) Section (f)(i)(B)(1) of Annex B of the Administrative Instructions requires that all alternatives of a Markush group have a common structure. In the instant case, the first claimed invention is a method claim which recites the diagnosis of thirteen different polymorphisms in a Markush type format. The separate methods of groups 1-9 have a common structure in that they all require analysis of the NK1R gene for polymorphisms, however, that common structure is not a contribution over the prior art. The NK1R gene was known in the art at the time the invention was made, as were methods for diagnosing polymorphisms in the gene (see, for example, Hopkins *et al.* Biochemical and Biophysical Research Communications, 1991, Vol. 180, No. 2, p. 110-117). Thus, the common structure which links groups 1-9 does not provide a "special technical feature" over the prior art. This reasoning applies to each of the different types of method claims provided in the claims.

(ii) Section (f)(i)(A) of Annex B of the Administrative Instructions requires that all alternatives of a Markush group have a common property or activity in order for Unity of Invention to be present. Although the methods of claims 1-5 share a common structure in that they all require analysis of the NK1R gene for polymorphisms, the set of methods is not regarded as being of a similar nature because all of the alternatives do not share a common property or activity. Each method is directed at looking for a distinct polymorphism whose structure is not the same as any of the alternative polymorphisms. Further, the set of polymorphisms are not joined by a common activity. While the particular effect of each of these polymorphisms is unknown, if any change in expression results from the presence or a particular allele in these polymorphic sites,

that effect would be specific to the particular polymorphism, and not a general function or effect shared by all thirteen individual polymorphisms. Thus, each of the methods of groups 1-9 are not joined by a common property or activity, and separation of these groups is proper under the governing PCT rules. This reasoning applies to each of the different types of method claims provided in the claims.

(iii) The particular products that comprise groups 10-18 are not joined by a common structure with one another. In this case, the products are each separately drawn to nucleic acid molecules which comprise particular nucleotides at particular positions in a reference sequence. Each of the nine separately recited products has a different particular structure from another (i.e. each claimed nucleic acid is different portion of a the NK1R gene with a particular nucleotide at a given position). These products are not joined by a special technical feature because they are each comprised of their own unique nucleic acid structure that is particular to the polymorphism of interest. Furthermore, these products are properly separated from the methods comprised in claims 1-5 because there is not a 1:1 correlation between the broadest method claim and the products recited in claims 7-11 since the methods of claim 1 do not require the use of the particular products of claim 7. Thus, there is no shared technical feature between the broadest embodiment of the method claims and the product claims.

(iv) Each of the methods recited in the instant claims are properly separated from one another because they are multiple processes of use. 37 CFR 1.475 states that "If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned

in the claims of the application and the first recited invention of each other category related thereto will be considered as the main invention of the claims." The methods of claim 6 requires an additional step of assessing the predisposition or susceptibility of an individual to a disease mediated by NK1R that is not required by any of the other methods recited herein. The methods of claim 13 are directed towards a method of treatment and require a treating step not required by the other methods. The methods of claim 14 are directed towards the preparation of a medicament and would thus require the steps of preparing the medicament that are not mentioned or required by the other claims. The methods of claims 17-18 are directed towards sequence identification and include a comparison step to another nucleic acid sequence that is not required by the other claims. Thus, under lack of unity practice each of these methods is properly separated one from another.

(v) The antagonist drugs of claim 15 are not joined to any of the other product claims because they have a different structure from the nucleic acids and have a different function from the nucleic acids in that the nucleic acids encode polypeptides while the drugs of claim 15 are NK1R antagonists.

(vi) The allelic variant polypeptide of claim 12 is not joined to any of the other product claims because it has a different structure from the nucleic acids and have a different function from the nucleic acids in that the nucleic acids encode polypeptides while the allelic variant of claim 12 is itself a polypeptide. Nucleic acids are composed of nucleotides while polypeptides are composed of amino acids. Furthermore, the polypeptide of claim 12 is joined to the drug of

claim 15 because the drug of claim 15 is directed towards the modulation of the polypeptide of claim 12 and is itself structurally and functionally separate from the polypeptide of claim 12.

(vii) The computer readable form of claim 16 has a special technical feature in that it is in fact a computer readable form.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1634

June 17, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600